Initial Approval: July 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Multiple Sclerosis Agents

PROVIDER GROUP: Pharmacy
Professional

MANUAL GUIDELINES: All dosage forms of the medications listed in Table 1 below will require prior authorization.

CRITERIA FOR INITIAL APPROVAL FOR ALL PRODUCTS: (must meet all of the following)

- Patient must have a diagnosis of a relapsing form of multiple sclerosis (MS).
  - For Ocrevus – patient must have a diagnosis of relapsing or primary progressive forms of MS (i.e. RRMS or PPMS)
- Medication must be prescribed within an FDA-approved age range.
- Medication must be prescribed by or in consultation with a neurologist.
- Dose and frequency of medication requested must be consistent with FDA-approved labeling.
- Patient must not be on concurrent therapy with another disease modifying MS agent (defined in table 2)
- Prescriber must attest that all additional medication-specific safety criteria, as defined in table 1, is met.

CRITERIA FOR RENEWAL FOR ALL PRODUCTS: (must meet one of the following)

- Prescriber must attest that the patient has received clinical benefit from continuous treatment with the requested medication.
- Prescriber must attest that all additional medication-specific safety criteria, as defined in table 1, is met.

LENGTH OF APPROVAL: 12 months

TABLE 1. MEDICATION-SPECIFIC CRITERIA

MEDICATION	AGE (years)	QUANTITY LIMIT	MEDICATION-SPECIFIC SAFETY CRITERIA
Ampyra® (dalfampridine)	≥18	2 units/day	➢ Patient must not have a seizure disorder. ➢ Patient must not have renal failure or renal impairment defined as CrCl ≤ 50 mL/min.
Aubagio® (teriflunomide)	≥18	1 unit/day	➢ Patient must not be taking leflunomide concurrently ➢ Female patients must use contraception concurrently with Aubagio and must have a negative pregnancy test within 30 days prior to initiation of therapy ➢ Patient must be evaluated for latent tuberculosis (TB) with a TB skin test prior to initial prior authorization approval
Avonex (interferon beta-1a)	≥18	1 kit (4 units)/28 days	
Betaseron (interferon beta-1b)	≥18	1 kit (14 units)/28 days	
Copaxone® (glatiramer)	≥18	1 kit (12 or 30 units)/30 days	
Extavia (interferon beta-1b	≥18	1 kit (15 units)/30 days	
Gilenya® (fingolimod)	≥10	1 unit/day	➢ Patient must not have any of the following: o Myocardial infarction in past 6 months, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, and class III/IV heart failure o Morbitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (unless a pacemaker is being used) o Baseline QTC interval ≥ 500 ms o Concurrent therapy will Class Ia or Class III antiarrhythmic medications in the past 45 days ➢ Patient must not be John Cunningham Virus (JCV) positive

TABLE 1 (CONT.). MEDICATION-SPECIFIC CRITERIA

MEDICATION	AGE (years)	QUANTITY LIMIT	MEDICATION-SPECIFIC SAFETY CRITERIA
Glatopa® (glatiramer)	≥18	1 kit (12 or 30 units)/30 days	
Lemtrada® (alemtuzumab)	≥17	60 mg total 1st cycle; 36 mg total 2nd cycle (1 year later)	➢ Patient must have had an inadequate response to two or more drugs indicated for the treatment of MS ➢ Patient must not have human immunodeficiency virus (HIV) ➢ Patient must have the following lab test completed prior to initial approval: o CBC, serum creatinine level, urinalysis with urine cell counts, thyroid function
Ocrevus™ (ocrelizumab)	≥18	300 mg day 1, 300 mg 2 weeks later, 600 mg every 6 months	➢ Patient must not have active hepatitis B virus (HBV), confirmed by positive results for HBsAg and anti-HBV tests
Plegridy (interferon beta-1a)	≥18	1 kit (2 units)/28 days	
Rebif (interferon beta-1a)	≥18	1 kit (12 units)/28 days	
Tecfidera® (dimethyl fumarate)	≥18	2 units/day	➢ Prescriber must monitor CBC with differential at baseline and every 6 months (or earlier if clinically indicated). o Absolute lymphocyte count should not be <500
Tysabri® (natalizumab)	≥18	300 mg/28 days	➢ Patient, prescriber and infusion center must be registered with the MS Touch Program **For a diagnosis of Crohn's disease, please see the Immunomodulators criteria*

TABLE 2. DISEASE-MODIFYING MS AGENTS

MEDICATION
Ampyra® (dalfampridine)
Aubagio® (teriflunomide)
Avonex (interferon beta-1a)
Betaseron (interferon beta-1b)
Copaxone® (glatiramer)
Extavia (interferon beta-1b
Gilenya® (fingolimod)
Glatopa® (glatiramer)
Mitoxantrone
Lemtrada® (alemtuzumab)
Ocrevus™ (ocrelizumab)
Plegridy (interferon beta-1a)
Rebif (interferon beta-1a)
Tecfidera® (dimethyl fumarate)
Tysabri® (natalizumab)

TABLE 3. COVERED PROVIDER GROUP

PROVIDER GROUP	MEDICATION
Pharmacy	Ampyra, Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Plegridy, Rebif, Tecfidera
Professional	Avonex, Betaseron, Copaxone, Extavia, Glatopa, Lemtrada, Ocrevus, Plegridy, Rebif, Tysabri,

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE